IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

ASTRAZENECA PHARMACEUTICALS LP, Plaintiff, v. MICHAEL T. HILGERS, in his official capacity as the ATTORNEY GENERAL OF THE STATE OF NEBRASKA; Defendant.	**CASE NO. _____** **COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

1. Section 340B of the federal Public Health Service Act, 42 U.S.C. § 256b, requires pharmaceutical manufacturers to "offer" their products at steeply discounted rates to an enumerated and clearly defined list of "covered entities." Because such price controls can disincentivize innovation and destabilize markets, Congress carefully crafted Section 340B and limited participation in the program to fifteen—and only fifteen—types of covered entities. Off-site, for-profit pharmacy chains (like CVS or Walgreens) were *not* included on the list of covered entities.

2. In fact, federal courts have already rebuffed efforts to force manufacturers to offer 340B-discounted drugs for sales occurring through these so-called "contract pharmacies." The U.S. Court of Appeals for the Third Circuit held that AstraZeneca's decision to restrict the offer of 340B-discounted drugs for contract pharmacy sales "do[es] not violate Section 340B," and it "enjoin[ed] [federal officials] from enforcing against" AstraZeneca any "reading of Section 340B" that would require AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 706 (3d Cir.

2023). The Third Circuit's decision was then incorporated into a permanent injunction, issued by the federal district court in Delaware, protecting AstraZeneca's right to proceed with its contract pharmacy policy.

3. The D.C. Circuit has joined the Third Circuit, similarly "reject[ing] [the] position that section 340B prohibits drug manufacturers from imposing any conditions on" the offer of "discounted drugs to covered entities" who use contract pharmacies. *Novartis Pharms. Corp. v. Johnson*, 102 F.4th 452, 459 (D.C. Cir. 2024).

4. Apparently dissatisfied with the scope of federal law, on April 9, 2025, the State of Nebraska enacted a statute seeking to achieve under state law precisely the same result that federal courts have resoundingly rejected. Known as LB 168, the Nebraska statute requires pharmaceutical manufacturers to offer 340B-discounted pricing for sales at an unlimited number of contract pharmacies.

5. The Nebraska statute prohibits manufacturers from "either directly or indirectly, deny[ing], restrict[ing], or prohibit[ing] the acquisition of any 340B drug by or delivery of any 340B drug to any location authorized by any 340B entity to receive such 340B drug, unless receipt of such 340B drug is prohibited by federal law." LB 168 § 3(a). LB 168 thus extends Section 340B's price caps beyond the scope of the federal program to reach unlimited contract pharmacy sales—in effect, vastly expanding discounts under the federal 340B program to an entirely new category of transactions. This expansion under state law directly conflicts with federal law.

6. Plaintiff AstraZeneca Pharmaceuticals LP brings this action to enjoin enforcement of LB 168. Although the Eighth Circuit rejected a constitutional challenge brought by the trade association PhRMA to an Arkansas statute that also required discounts for contract pharmacy sales, *see PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024), AstraZeneca does not rely here on

the claims asserted in that litigation. Instead, AstraZeneca argues that LB 168 cannot validly be enforced against AstraZeneca for four separate and independent reasons.

7. ***First***, LB 168 creates a conflict with—and thus is preempted by—federal patent law. In *Biotechnology Industry Organization* (*BIO*) *v. District of Columbia*, the Federal Circuit squarely held that federal patent law "prohibits states from regulating the price of patented goods." 496 F.3d 1362, 1372 (Fed. Cir. 2007). Yet LB 168 does precisely that. It requires manufacturers like AstraZeneca to offer steeply discounted prices for the sale of their patented drugs, thereby extending federal price caps to an additional category of patented drug sales (contract pharmacy sales) that federal courts have held fall *outside* of the 340B program.

8. ***Second***, even though federal courts have held that a manufacturer has a right under federal law to reasonably condition its "offer" of discounted drugs under Section 340B on the submission of claims data, LB 168 directly prohibits manufacturers from imposing such conditions. Claims data is important to the functioning of the federal program: Section 340B gives manufacturers the right to audit covered entities who divert discounted drugs to non-patients, but manufacturers must have "reasonable cause" before initiating an audit. By prohibiting manufacturers from obtaining the data necessary to identify unlawful diversion of 340B-priced drugs and establish reasonable cause, LB 168 inhibits manufacturers' ability to exercise their statutory audit rights. Claims data is also necessary for manufacturers to avoid duplicate discounts under the 340B program and the Medicare Drug Price Negotiation Program. LB 168's prohibition on acquiring claims data thus creates a conflict with—and is preempted by—federal law.

9. ***Third***, LB 168 violates the Contracts Clause of the U.S. Constitution. *See* U.S. Const. art. I, § 10, cl. 1. The 340B program is enforced through agreements between drug manufacturers and the Secretary of the U.S. Department of Health and Human Services (HHS).

42 U.S.C. § 256b(a)(1). LB 168 substantially interferes with the operation of those agreements, and with manufacturers' rights and obligations thereunder, by imposing costly new obligations only on manufacturers who sign such agreements.

10. ***Fourth***, LB 168 violates the U.S. Constitution's Takings Clause. *See* U.S. Const. amend. V. Under the Takings Clause, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo v. City of New London*, 545 U.S. 469, 477 (2005). But LB 168 requires manufacturers like AstraZeneca to transfer their property (prescription drugs) to other private parties (covered entities and the pharmacies with which they contract). This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. But in fact they are not: Manufacturers are compensated at steeply discounted prices, well below fair market value.

11. AstraZeneca therefore seeks an order: (1) declaring that LB 168 is preempted by federal patent law as applied to AstraZeneca's patented products; (2) declaring that LB 168's data-collection restriction is preempted by Section 340B; (3) declaring that LB 168 is unconstitutional as applied to AstraZeneca under the federal Contracts Clause; (4) declaring that LB 168 is unconstitutional as applied to AstraZeneca under the federal Takings Clause; and (5) enjoining Defendant Nebraska Attorney General Mike Hilgers and any other Nebraska officials from enforcing LB 168 against AstraZeneca through investigative demands, administrative proceedings, lawsuits seeking civil penalties or other relief, or in any other manner.

JURISDICTION AND VENUE

12. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the Constitution of the United States) and 28 U.S.C. § 1338(a) (civil action arising under any Act of Congress relating to patents). An actual controversy exists between the parties within the meaning

of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201-02.

13. This Court also has inherent equitable powers to enjoin actions of state officials that contradict the federal Constitution or federal law. *See Ex parte Young*, 209 U.S. 123, 159-60 (1908); *accord, e.g.*, *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689 (1949).

14. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because this action challenges a Nebraska law that applies to and purports to regulate the sale of AstraZeneca's products in this District. AstraZeneca makes its drugs available and sells its products to multiple 340B-covered entities within this District, and these entities maintain multiple contract pharmacy arrangements. The challenged law (if not invalidated) would apply to conduct and property in this District, including AstraZeneca's, and is highly likely to be enforced in this District.

15. Venue is also proper in this Court under 28 U.S.C. § 1391(b)(1) because Defendants maintain offices in this District, through which Defendants would enforce the law challenged in this action.

PARTIES TO THE ACTION

16. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware. AstraZeneca is a biopharmaceutical company focusing on the discovery, development, manufacturing, and commercialization of medicines. AstraZeneca participates in the 340B program.

17. Defendant Michael T. Hilgers is the Attorney General of Nebraska. In that role, he enforces the challenged legislation. This suit is brought against him in his official capacity only. The Attorney General maintains an office in Lincoln, Nebraska.

FACTUAL ALLEGATIONS

The Federal 340B Program Caps Drug Prices for Enumerated Covered Entities that Provide Healthcare to Certain Underserved Populations

18. Section 340B of the Public Health Service Act established a federal program that "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities," known as covered entities, that provide healthcare to certain underserved populations. *Astra USA, Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

19. As a condition of receiving coverage and reimbursement for its drugs under Medicaid and Medicare Part B, a pharmaceutical manufacturer must enter into a pharmaceutical pricing agreement with HHS. 42 U.S.C. § 256b(a)(1). In that agreement, the manufacturer must "offer each covered entity covered outpatient drugs for purchase" at a specified discount price "if such drug is made available to any other purchaser at any price." *Id.* This is known as Section 340B's "must-offer" requirement. Manufacturers that "knowingly and intentionally charge[] a covered entity a price for purchase of a drug that exceeds the [340B discount price]" are subject to civil monetary penalties. *Id.* § 256b(d)(1)(B)(vi)(III). The 340B statute also regulates covered entities, which may not obtain 340B pricing on units of drugs for which a manufacturer pays a Medicaid rebate (known as "duplicate discounts"), nor resell or otherwise transfer such drugs to persons other than their patients (known as "diversion"). *Id.* § 256b(a)(5)(A), (B).

20. Congress enacted Section 340B to give covered entities access to prescription drugs at below-market prices, thereby helping them serve their uninsured and indigent patients. H.R. Rep. No. 102-384, pt. 2, at 7 (1992). Balanced against its goal of increasing access, however, Congress also recognized the need to "assure the integrity of the drug price limitation program." *Id.* at 16.

21. Congress has added to the list of 340B-covered entities over time, and today there are fifteen delineated categories of covered entities. 42 U.S.C. § 256b(a)(4)(A)-(*O*).

22. Notably, Congress has *never* included contract pharmacies in the statutorily defined list of facilities that qualify as covered entities. Indeed, in drafting what would become the 340B statute, Congress considered proposed language that would have permitted covered entities to dispense 340B drugs through *on-site* contractors providing pharmacy services. *See* S. Rep. No. 102-259, at 1-2 (1992) (requiring manufacturers to provide a discounted price for drugs that are "purchased and dispensed by, or under a contract entered into for *on-site pharmacy services* with" certain enumerated covered entities) (emphasis added). But that provision was not enacted.

23. The 340B program has its own federal enforcement provisions and administrative dispute-resolution process. Congress required the Secretary of HHS to establish an adjudicatory body to resolve disputes among participants in the 340B program, including "claims by covered entities that they have been overcharged for drugs purchased under this section [340B], and claims by manufacturers … of violations" by covered entities. 42 U.S.C. § 256b(d)(3)(A). Under that statutory mandate, the Health Resources and Services Administration (HRSA), the subagency of HHS that oversees the 340B program, has established "requirements and procedures for the 340B Program's administrative dispute resolution (ADR) process." 85 Fed. Reg. at 80,632 (Dec. 14, 2020). The ADR Rule authorizes panels of federal officers to resolve claims for "monetary damages," as well as other unspecified "equitable relief" sought by claimants. 42 C.F.R. § 10.21(a). And it empowers ADR panels to address a range of factual and legal disputes, including "those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales." 85 Fed. Reg. at 80,636.

24. Importantly, before a manufacturer may access the ADR process, HRSA requires the manufacturer to first audit a covered entity. *See* 42 U.S.C. § 256b(d)(3)(B)(iv); 89 Fed. Reg. 28,643, 28,645 (Apr. 19, 2024) ("[M]anufacturers are required to audit a covered entity prior to filing an ADR claim"). And under HRSA regulations, a manufacturer may only initiate an audit when it can point to "documentation which indicates that there is reasonable cause," with "reasonable cause" defined to mean "that a reasonable person could believe that a covered entity may have violated" the prohibitions on diversion or duplicate discounting. 61 Fed. Reg. 65,406, 65,409 (Dec. 12, 1996). Thus, absent such "documentation," the ADR process is unavailable to a manufacturer.

25. HRSA revised the ADR Rule last year. *See* 89 Fed. Reg. at 28,643. Among other things, the revised rule gives "340B ADR Panel[s]" responsibility to resolve disputes related to "overcharge[s]," which include claims that a manufacturer has "limited [a] covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling prices." 42 C.F.R. §§ 10.3, 10.21.

Contract Pharmacy Use Leads to Abuse and Profiteering

26. Section 340B does not require manufacturers to offer 340B-discounted drugs to contract pharmacies—or indeed, to *any* entity not specifically enumerated in the statute. In the decades since the enactment of the program, however, HRSA has issued two non-binding "guidance" documents purporting to authorize covered entities to enter into agreements with contract pharmacies to dispense outpatient drugs under Section 340B.

27. In 1996, HRSA issued guidance providing that "eligible covered entities that do not have access to appropriate 'in-house' pharmacy services" could now enter into an agreement with a *single* outside pharmacy of its choice to provide such services for 340B drugs. 61 Fed. Reg. 43,549, 43,555 (Aug. 23, 1996) (1996 Guidance).

28. Then, in 2010, HRSA released new guidance stating that covered entities could now "use multiple pharmacy arrangements"—that is, an *unlimited* number of contract pharmacies, without any geographic limits—"as long as they comply with guidance developed to help ensure against diversion and duplicate discounts and the policies set forth regarding patient definition." 75 Fed. Reg. 10,272, 10,273 (2010 Guidance). The 2010 Guidance thus purported to authorize a covered entity to enter into an unlimited number of contract pharmacy arrangements anywhere in the United States.

29. The 2010 Guidance triggered a massive surge in the number of contract pharmacies receiving and distributing 340B drugs. *See Novartis Pharms.*, 102 F.4th at 457 (noting a "significant expansion"). In 2018, the Government Accountability Office reported that the number of contract pharmacies had ballooned from 1,300 in 2010, to nearly 20,000 in 2017. U.S. Gov't Accountability Off., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* 2 (June 2018) (2018 GAO Report), https://www.gao.gov/assets/700/692697.pdf. These numbers have continued to grow. Today, more than 33,000 different pharmacies participate in the 340B program, with more than 194,000 individual contracts. Adam J. Fein, Drug Channels Inst., *Exclusive: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market* (Jul. 11, 2023), https://www.drugchannels.net/2023/07/exclusive-for-2023-five-for-profit.html. The vast majority of these contract pharmacies (75% as of 2018) are for-profit retail chain pharmacies; and the five largest national pharmacy chains—CVS, Walgreens, Walmart, Rite-Aid, and Kroger—accounted for a combined 60% of all 340B contract pharmacies, even though these chains represent only 35% of all pharmacies nationwide. 2018 GAO Report at 20-21.

30. Make no mistake, the boom in contract pharmacies has been fueled by the prospect of outsized profit margins on 340B-discounted drugs. As the D.C. Circuit explained:

> While some contract pharmacies maintain separate inventories of section 340B drugs, most fill prescriptions from inventories that intermingle discounted and non-discounted drugs. Only after dispensing the drugs do these pharmacies attempt to discern whether individual customers were patients of covered entities—in other words, whether individual prescriptions were eligible for the discount. Many pharmacies outsource this determination to third-party administrators, who often receive a larger fee for every prescription deemed eligible for the discount. Once the pharmacy or the administrator categorizes a certain number of prescriptions as eligible, the pharmacy places an order to replenish its section 340B purchases. The covered entity, the pharmacy, and the third-party administrator often divvy up the spread between the discounted price and the higher insurance reimbursement rate. Each of these actors thus has a financial incentive to catalog as many prescriptions as possible as eligible for the discount.

Novartis Pharms., 102 F.4th at 457-58; *see* Decl. of Krista M. Pedley ¶¶ 5-9, *Sanofi-Aventis U.S., LLC v. HHS*, No. 3:21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2. Since a 340B discount is applied for the contract pharmacy sale—even though the sale has *also* benefitted from the full insurance reimbursement—this dynamic results in substantial arbitrage revenues. *See Sanofi*, 58 F.4th at 699 ("[T]hey turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount."). And though the pharmacy may share some of its windfall with the covered entity (or the covered entity's vendor), *the patient* has still paid the full out-of-pocket amount designated under his or her insurance policy.

31. As Senator Chuck Grassley put it in a letter to HRSA, for-profit pharmacies "are reaping sizeable 340B discounts on drugs and then turning around and upselling them to fully insured patients covered by Medicare, Medicaid, or private health insurance in order to maximize their spread." Letter from Sen. Chuck Grassley, S. Comm. on the Judiciary, to Mary K. Wakefield, Adm'r, HRSA (Mar. 27, 2013), https://www.grassley.senate.gov/download/2013-03-27-ceg-to-hrsa-340b-oversight-3. This "spread" means contract pharmacies retain up to $5 billion in annual profits from 340B sales. *See* Neal Masia, *340B Drug Pricing Program: Analysis Reveals $40*

Billion in Profits in 2019, Alliance for Integrity & Reform (May 2021), http://bit.ly/4bM7sHE; Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy*, Am. J. of Managed Care (May 4, 2022), https://bit.ly/4c61Do6 (five contract pharmacies "earn about $3.2 billion in gross profits from 340B"); Walgreens Boots Alliance, Inc., Form 10-K (Oct. 15, 2020), https://bit.ly/3KveDrI (noting that "[c]hanges in pharmaceutical manufacturers' . . . distribution policies . . . in connection with the federal 340B drug pricing program[] could . . . significantly reduce [Walgreens's] profitability"); Rebecca Pifer, *Hospitals, PBMs Say Drugmaker Restrictions on 340B Discounts Stifling Finances*, HealthcareDive (May 5, 2020), https://bit.ly/3P9xmdF (reporting that CVS Health "said its 340B product lines were stagnant" after contract-pharmacy restrictions were imposed).

32. Although some of the money generated through contract pharmacy sales is passed on to covered entities, most of these profits are *not* going to federally qualified health centers or other federal grantees that provide services to underserved populations (such as black lung clinics, hemophilia treatment centers, urban Indian health organizations, and AIDS drug purchasing assistance programs). Instead, they are being captured by 340B hospitals and contract pharmacies, which are responsible for nearly 90% of all 340B purchases. Aaron Vandervelde et al., Berkeley Rsch. Grp., *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa.

33. Nor are these huge profits being passed on to patients. For example, in response to a 2018 GAO survey, 45% of covered entities admitted they do not pass along *any* discount to *any* patients that use *any* of their contract pharmacies. 2018 GAO Report at 30. As for the remaining 55%, the GAO noted that entities using contract pharmacies may provide discounts to patients only in limited cases. *Id*. Likewise, the HHS Office of Inspector General found in 2014 that some

contract pharmacies do not offer 340B-discounted prices to uninsured patients at all. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014) (2014 OIG Report), https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.* By contrast, the GAO noted that 17 of 23 of the surveyed covered entities that had *in-house* pharmacies reported offering discounts at those pharmacies. 2018 GAO Report at 30 n.46. Most recently, a report by the Senate Committee on Health, Education, Labor & Pensions found that major covered entities do not directly pass on 340B discounts to patients, with one entity stating to the Committee that "reducing patients' drug expenses is not the purpose of the 340B Program." S. Comm. on Health, Educ., Labor & Pensions, *Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program* 9 (Apr. 2025), https://www.help.senate.gov/imo/media/doc/final_340b_majority_staff_reportpdf.pdf.

34. In short, the widespread proliferation of contract pharmacy arrangements since 2010 has transformed the 340B program from one intended to assist vulnerable patients into a multi-billion-dollar arbitrage scheme.

35. At the same time, the explosive growth of contract pharmacy arrangements also has facilitated increased diversion and duplicate discounts. *See Novartis Pharms.*, 102 F.4th at 458. A 2011 report from the Government Accountability Office warned that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." U.S. Gov't Accountability Off., GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 28, (Sept. 23, 2011), https://www.gao.gov/assets/330/323702.pdf. The report further found that

"HRSA's oversight of the 340B program is inadequate because it primarily relies on participants' self-policing to ensure compliance." *Id.* at 21.

36. These structural problems have only intensified over time, as the use of multiple contract pharmacies has become rampant. The 2014 OIG report determined that self-policing by covered entities has been insufficient to stop these abuses, since "most covered entities . . . do not conduct all of the oversight activities recommended by HRSA." 2014 OIG Report at 2. The 2018 GAO Report similarly criticized the continuing "weaknesses in HRSA's oversight [that] impede its ability to ensure compliance with 340B Program requirements at contract pharmacies." 2018 GAO Report at 45.

37. Indeed, HRSA's own audits of covered entities continue to identify numerous instances of abuse. The 2018 GAO Report observed that "66 percent of the 380 diversion findings in HRSA audits [between 2012 and 2017] involved drugs distributed at contract pharmacies." *Id.* at 44. And based on information from HRSA's website, over 25% of covered entities audited since 2017 have had at least one finding related to contract pharmacy noncompliance. Indeed, out of 199 audits conducted in 2019, HRSA discovered dozens of instances of duplicate discounts, as well as evidence that at least 19 covered entities had permitted diversion of 340B drugs through contract pharmacies. *See* HRSA, *Program Integrity: FY19 Audit Results*, https://www.hrsa.gov/opa/program-integrity/audit-results/fy-19-results.

AstraZeneca's 340B Policy and Resulting Litigation

38. Against this legal and factual backdrop, in August 2020, AstraZeneca announced to covered entities that, effective October 1, 2020, it would revert to the contract pharmacy approach set forth in HRSA's 1996 Guidance.

39. Under this policy, AstraZeneca continues to make its products available at 340B-discounted prices—in unlimited quantities—to all covered entities. For covered entities that do not

maintain their own on-site dispensing pharmacy, AstraZeneca offers discounted drugs for sales at a single contract pharmacy site for each covered entity. But AstraZeneca no longer makes 340B discounts available for drugs sold at an unlimited number of contract pharmacies.

40. AstraZeneca's policy is consistent with the letter and intent of the 340B program—limiting the potential for abuse, while still enabling all covered entities and their patients to continue to access AstraZeneca's medicines at 340B prices. Under AstraZeneca's policy, over 13,000 covered entities that lack an on-site pharmacy have registered a contract pharmacy to which AstraZeneca continues to make 340B discounts available, including numerous covered entities in Nebraska. AstraZeneca is committed to working with all covered entities to ensure that every patient can obtain needed medicines at prices they can afford.

41. In response to AstraZeneca's new contract pharmacy policy and other manufacturers' adoption of similar policies, HHS and HRSA issued an Advisory Opinion on December 30, 2020, asserting that the 340B statute requires manufacturers to offer 340B-discounted drugs for sales at unlimited contract pharmacies.

42. In early 2021, AstraZeneca filed suit in the U.S. District Court for the District of Delaware against HHS and HRSA, challenging the Advisory Opinion. On June 16, 2021, the Delaware court issued a detailed opinion finding the Advisory Opinion unlawful. *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47 (D. Del. 2021). The court concluded that Section 340B "says nothing about the permissible role (if any) of contract pharmacies," and that, in light of this "total omission," the Advisory Opinion's attempt to impose an obligation on AstraZeneca to make discounted drugs available for sales at unlimited contract pharmacies was "legally flawed." *Id.* at 59. The agency withdrew the Advisory Opinion following the Delaware court's ruling.

43. In a second ruling, the Delaware court addressed AstraZeneca's challenge to a "violation letter" issued by HRSA, which adopted the same position as the Advisory Opinion. The court again rejected the agency's view that Section 340B obligates drug manufacturers to make 340B-discounted drugs available for unlimited contract pharmacy sales. *AstraZeneca Pharms. LP v. Becerra*, No. 21-cv-27, 2022 WL 484587 (D. Del. Feb. 16, 2022). The court reiterated "key points" from its prior opinion, including that Congress "did not clearly intend for drug manufacturers to be required to facilitate sales of covered drugs for dispensing by an unlimited number of contract pharmacies." *Id.* at *5-*6.

44. On January 30, 2023, the U.S. Court of Appeals for the Third Circuit affirmed the Delaware court's rulings. In a consolidated opinion addressing AstraZeneca's case and appeals in parallel actions by other manufacturers, the Third Circuit held that the Advisory Opinion and violation letter are "unlawful," and it "enjoin[ed] HHS from enforcing [it] against" AstraZeneca. *Sanofi*, 58 F.4th at 706. The court of appeals also held that AstraZeneca's policy of not offering discounts for sales at unlimited "contract pharmacies do[es] not violate Section 340B." *Id.*

45. The government neither sought en banc review of the Third Circuit's decision nor filed a petition for certiorari in the U.S. Supreme Court.

46. On May 5, 2023, the Delaware court issued a final judgment in AstraZeneca's case, to which the government stipulated. The court's order provides that it is:

a. "DECLARED that Advisory Opinion 20-06 and the Violation Letter from the Health Resources and Services Administration to Plaintiff AstraZeneca Pharmaceuticals LP (AstraZeneca), dated May 17, 2021 (Violation Letter), are unlawful;

b. DECLARED that AstraZeneca's policy limiting the use of contract pharmacies under Section 340B of the Public Health Service Act (Section 340B), 42 U.S.C.

§ 256b—namely, that covered entities may use an in-house pharmacy and, if they do not have an in-house pharmacy, they may use one contract pharmacy—does not violate Section 340B;

c. ORDERED that the Violation Letter is VACATED as contrary to law pursuant to 5 U.S.C. § 706;

d. ORDERED that Defendants, including their officers, agents, and employees, are ENJOINED from enforcing against AstraZeneca the agency's reading of Section 340B as requiring delivery of discounted drugs to an unlimited number of contract pharmacies."

Final Judgment at 1, *AstraZeneca*, No. 1:21-cv-27 (D. Del. May 5, 2023), ECF No. 123.

47. As a result of the Third Circuit's ruling and the Delaware court's injunction, AstraZeneca is entitled to proceed with its lawful contract pharmacy policy.

Numerous States Enact Legislation Requiring Manufacturers to Make 340B-Discounted Drugs Available for Unlimited Contract Pharmacy Sales

48. While AstraZeneca's lawsuit about the use of contract pharmacies in the 340B program was already underway, Arkansas enacted Act 1103, titled the 340B Drug Pricing Nondiscrimination Act, which seeks to require manufacturers to make 340B-discounted drugs available for unlimited contract pharmacy sales. Numerous states—including Missouri, Kansas, Louisiana, Maryland, Minnesota, Mississippi, Tennessee, New Mexico, South Dakota, North Dakota, Utah, and West Virginia—have since followed suit. And lawsuits challenging those state laws on constitutional grounds have been filed by drug manufacturers, including AstraZeneca, as well as Pharmaceutical Research and Manufacturers of America (PhRMA), a trade organization that AstraZeneca recently rejoined.

49. In Arkansas, PhRMA challenged Arkansas Act 1103, arguing that the law is (1) preempted by Section 340B; and (2) invalid under the Dormant Commerce Clause. *See PhRMA v. McClain*, 645 F. Supp. 3d 890, 893-94 (E.D. Ark. 2022). PhRMA did not argue that Act 1103 is preempted by the federal patent laws or invalid under the Contracts Clause and Takings Clause, nor did PhRMA raise any claim regarding manufacturer data collection, which Act 1103 does not address. The district court rejected PhRMA's preemption challenge and stayed its Commerce Clause challenge.

50. The U.S. Court of Appeals for the Eighth Circuit affirmed that decision, holding that Section 340B does not preempt Act 1103. *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024). The Eighth Circuit did not consider or decide whether Section 340B preempts state data-collection restrictions or whether the federal patent laws preempt Act 1103; nor did the Court consider or decide whether Act 1103 violates the Contracts Clause or the Takings Clause. Moreover, the Eighth Circuit did not consider the effect of the federal court injunction precluding interference with AstraZeneca's contract pharmacy policy.

51. Central to the Eighth Circuit's ruling that Section 340B does not preempt Act 1103 were two factual assumptions regarding the relationship between covered entities and contract pharmacies: first, that "[c]overed entities maintain legal title to the 340B drugs" when they are acquired by contract pharmacies, *id.* at 1142; *see id.* at 1144; and second, that a contract pharmacy acts as "an agent of the covered entity" with respect to the sale of 340B drugs, *id.* at 1142. Those factual assumptions were foundational to the Court's conclusion that, under Act 1103, "[p]harmacies do not purchase 340B drugs, and they do not receive the 340B price discounts." *Id.* at 1144.

52. Both factual assumptions are incorrect. Although HRSA has issued guidance instructing covered entities that they should "retain[] title" to drugs acquired by contract pharmacies, 61 Fed. Reg. at 43,553, in reality they usually do not. As HRSA's Director of Pharmacy Affairs has explained, under typical contract-pharmacy arrangements, 340B-discounted drugs are "placed on the shelf" as "'neutral inventory'"—that is, placed into "the contract pharmacy's *own inventory*," just like any other drugs—and can "be dispensed [by the pharmacy] to *any subsequent patient*" of the pharmacy, regardless of whether that patient is associated with a covered entity. Decl. of Krista M. Pedley ¶¶ 5, 10-11, *Sanofi-Aventis U.S., LLC v. HHS*, No. 21-cv-634 (D.N.J. June 24, 2021), ECF No. 93-2 (emphases added). Thus, in practice, title to 340B drugs is transferred to the contract pharmacy rather than maintained by the covered entity.

53. Nor is it correct that the typical contract pharmacy acts as "an agent of the covered entity" with respect to the sale of 340B drugs. *PhRMA*, 95 F.4th at 1142. Publicly available information indicates that contract pharmacies are usually independent contractors, not agents, with respect to the acquisition and sale of 340B drugs. *See, e.g.*, 340B Contract Pharm. Servs. Agreement between Jackson Mem'l Hosp. & Walgreens, at 87, https://bit.ly/4kX06Wb ("Independent Contractor" provision disclaiming "any relationship between the parties hereto other than that of independent entities contracting").

Nebraska Enacts Legislation Requiring Manufacturers to Make 340B-Discounted Drugs Available for Unlimited Contract Pharmacy Sales

54. On April 3, 2025, the Nebraska Legislature passed LB 168, which Governor Jim Pillen signed into law on April 9, 2025.

55. Because the legislature declared that the law addresses an emergency, it took immediate effect upon signing by the Governor. *See* LB 168 § 7.

56. Entitled the "340B Contract Pharmacy Protection Act," LB 168 provides that a pharmaceutical manufacturer must not "either directly or indirectly, deny, restrict, or prohibit the acquisition of any 340B drug by or delivery of any 340B drug to any location authorized by any 340B entity to receive such 340B drug, unless receipt of such 340B drug is prohibited by federal law." LB 168 § 3(1). This provision does not identify a geographical limit to its coverage.

57. LB 168 does not prohibit diversion or otherwise require that drugs purchased at 340B-discounted prices be dispensed only to patients of a covered entity. *See* 42 U.S.C. § 256b(a)(5)(B) ("[A] covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). Nor does LB 168 account for HRSA's enforcement authority or for the congressionally mandated procedures for administrative dispute resolution. *See id.* § 256b(d)(3).

58. LB 168 empowers the Nebraska Attorney General "or any county attorney" to bring an action "for an injunction or other process" against manufacturers who purportedly violate the statute. *See* LB 168 § 4. There is no guarantee that this "other process" does not include criminal penalties.

59. The operation and apparent intent of LB 168 is to compel pharmaceutical manufacturers to make 340B discounts available for unlimited contract pharmacy sales, despite the Third and D.C. Circuits' holdings that federal law imposes no such requirement, and notwithstanding the Delaware court's injunction. LB 168 does not specify any source for the State's purported authority to add requirements to a comprehensive federal healthcare program.

60. Indeed, LB 168 in fact goes even further. The statute allows covered entities to demand that 340B drugs be sent to "*any* location authorized by any 340B entity to receive such 340B drug," LB 168 § 3(1) (emphasis added), not only to contract pharmacies. *Cf. Sanofi*, 58 F.4th

at 704 (rejecting federal government's argument that "drug makers must deliver where a covered entity demands, whether that be 'a neighborhood pharmacy' or 'the lunar surface").

61. LB 168 also restricts manufacturers' ability to collect data regarding the purchase and dispensing of 340B drugs by covered entities and contract pharmacies. The statute provides that "[a]ny manufacturer, agent or affiliate of such manufacturer, or third-party logistics provider shall not, either directly or indirectly, require any 340B entity to submit any data, including any claim data, utilization data, encounter data, medical data, purchasing data, or other data, as a condition for allowing the acquisition of any 340B drug by or delivery of any 340B drug to any 340B entity or to any location authorized by any 340B entity to receive such 340B drug, unless such data is required by federal law." LB 168 § 3(2). LB 168 does not acknowledge that collecting such claims data is a critical means for manufacturers to develop the "reasonable cause" that HRSA guidance requires before a manufacturer may audit a covered entity, 61 Fed. Reg. at 65,409, and is also necessary to identify sales that are eligible for the Medicare Drug Price Negotiation Program under the Inflation Reduction Act (IRA), s*ee* 42 U.S.C. § 1320f-2(d), in order to avoid duplicate discounts under both the 340B program and the IRA.

62. Importantly, although it uses the words "acquisition" and delivery," LB 168 does not actually regulate drug distribution; instead, it regulates access to 340B *discounts*. Because the law directly regulates "340B drug[s]," LB 168 on its face regulates pricing—and insofar as manufacturers are affected, *only* regulates pricing. In requiring manufacturers to provide access to 340B drugs, the statute confers access to *prices* that have been reduced under the statutory formula prescribed by Section 340B. The statute does not affect any other aspect of the acquisition or delivery of drugs—such as packaging requirements, shipping conditions, shipping costs, or other

logistics and specifications of drug delivery and acquisition. Indeed, pricing is the *only* thing that distinguishes a sale that complies with LB 168 from a sale that violates LB 168.

LEGAL ALLEGATIONS

LB 168 Is Preempted by Federal Patent Law as Applied to AstraZeneca's Patented Products

63. The Supremacy Clause of the U.S. Constitution provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof," are "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under the Supremacy Clause, "state law will be preempted when it conflicts with or frustrates federal law." *N. Nat. Gas Co. v. Iowa Utilities Bd.*, 377 F.3d 817, 820 (8th Cir. 2004). The doctrine of federal preemption that arises out of the Supremacy Clause requires that "any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield.'" *Felder v. Casey*, 487 U.S. 131, 138 (1988) (quoting *Free v. Bland*, 369 U.S. 663, 666 (1962)).

64. The Constitution gives Congress exclusive authority to establish a system of incentives "[t]o promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. Under the federal patent law, inventors are "impelled to invest in creative effort" on the promise that they will obtain "a federally protected 'exclusive right'" to sell their inventions for a limited period. *BIO*, 496 F.3d at 1372. The public can benefit from immediate access to new inventions during the exclusivity period; and after the period expires, the public gets "lower price[s] through unfettered competition." *Id.* at 1373. The States are not free to upset that finely calibrated system: "Where it is clear how the patent laws strike that balance in a particular circumstance, that is not a judgment the States may second-guess." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152 (1989).

65. State laws that cap or fix the prices at which patented drugs may be sold are accordingly preempted by federal patent law, as the Federal Circuit has explained, because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374. In *BIO*, the Federal Circuit struck down a District of Columbia law that prohibited patented drugs from "being sold in the District for an excessive price." *Id.* at 1365. The court explained that, notwithstanding "the District's judgment" that drug manufacturers were charging "excessive prices" that "threaten[ed] the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need," the law was "contrary to the goals established by Congress in the patent laws." *Id.* at 1365, 1374 (quoting D.C. Code § 28-4551). The District's law was therefore preempted because "[t]he underlying determination about the proper balance between innovators' profit and consumer access to medication . . . is exclusively one for Congress to make." *Id.* at 1374.

66. The same analysis applies to LB 168. Like the District of Columbia law invalidated in *BIO*, LB 168 restricts the prices at which manufacturers must offer their patented drugs by requiring them to make 340B discounts available for unlimited contract pharmacy sales. Whereas Section 340B caps drug prices with respect to sales to a limited set of specifically enumerated covered entities, LB 168 purports to extend those price caps to a category of sales—unlimited contract pharmacy sales—that federal courts have held fall *outside* of the federal program. Accordingly, LB 168 functions as a price cap for unlimited contract pharmacy sales, impermissibly constraining manufacturers' "opportunity" to take advantage of the benefit of exclusivity conferred by Congress "during the patent's term." *Id.* at 1372.

67. LB 168 is thus preempted by federal patent law as applied to AstraZeneca's patented products. States are not permitted to set the prices of patented drugs or to "re-balance" the "rewards and incentives" embodied in the federal patent laws, as Nebraska has done here. *Id.* at 1374.

LB 168's Data-Collection Restriction is Preempted by Section 340B

68. Insofar as LB 168 restricts manufacturers from obtaining 340B purchase and claims data from covered entities, it is also preempted by the 340B statute under the Supremacy Clause.

69. A state statute is preempted by federal law if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). In addition, States may not establish parallel regimes that encroach on the federal government's authority to set and define federal enforcement priorities. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-51 (2001).

70. LB 168 directly interferes with the robust federal enforcement regime that Congress has enacted for the 340B program, which includes the ADR process, required auditing provisions for manufacturers and covered entities, and the possibility of civil monetary penalties in the event of a manufacturer overcharge or diversion by a covered entity.

71. Indeed, LB 168 directly cuts off manufacturers' access to the federal enforcement regime. The law prohibits manufacturers from requiring covered entities and contract pharmacies "to submit any data, including any claim data, utilization data, encounter data, medical data, purchasing data, or other data." LB 168 § 3(2). But "manufacturers are required to audit a covered entity prior to filing an ADR claim," 89 Fed. Reg. at 28,645; *see* 42 U.S.C. § 256b(d)(3)(B)(iv), and a manufacturer must have "documentation" indicating diversion or duplicate discounts before it may initiate such an audit, 61 Fed. Reg. at 65,409. "By restricting the very method by which data collection is made," LB 168 "frustrates drug manufacturers' ability to take the initial steps

necessary to start the very audit required to access the alternative dispute resolution system." *PhRMA v. Morrisey*, 760 F.Supp.3d 439, 453 (S.D. W. Va. 2024); *see id.* (finding that a similar provision restricting audits unconstitutionally "stands as an obstacle to achieving the federal objective of preventing fraud in the 340B Program").

72. The data-collection restriction conflicts with federal law in other ways, too. Under the IRA, Congress has instructed HHS to "negotiate" with manufacturers for the "maximum fair price" that Medicare will pay for certain selected drugs. 42 U.S.C. § 1320f-3(a). Manufacturers must provide those selected drugs at the lower of the "maximum fair price" *or* the 340B price—but they have a right under federal law not to pay 340B discounts to drugs discounted under the IRA. *Id.* § 1320f-2(d) (manufacturers "shall not be required" to provide duplicate discounts). The Centers for Medicare and Medicaid Services (CMS), which administers the program, leaves it to manufacturers to prevent such duplicate price reductions by identifying when a drug is dispensed as a 340B drug. *See* CMS, Medicare Drug Pricing Negotiation Final Guidance 58-60 (Oct. 2, 2024), http://bit.ly/3Y719J0. But LB 168 bars manufacturers from obtaining the data they need to undertake this de-duplication process. LB 168 therefore deprives manufacturers of their rights under federal law.

73. While the data-collection restriction does not apply to "data [that] is *required* by federal law," LB 168 § 3(2) (emphasis added), it does not appear that this exception applies to claims data necessary to establish reasonable cause for an audit or to avoid duplicate discounts under the IRA. At the very least, the restriction significantly inhibits the data-collection process, increasing compliance costs and litigation risk.

74. In *Astra USA*, the Supreme Court held that private entities may not bring actions under state contract law to enforce the provisions of manufacturers' 340B pharmaceutical pricing

agreements. 563 U.S. at 113-14. "Congress made HHS administrator of . . . the 340B Program." *Id.* at 120. Suits by private entities, the Court explained, "would undermine the agency's efforts" to administer the program "harmoniously and on a uniform, nationwide basis." *Id.* "With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial." *Id.*

75. Yet LB 168 inserts Nebraska and its officials into a federal program that Congress carefully crafted, frustrates the accomplishment of Congress's objectives, and interferes with Congress's chosen methods of oversight and enforcement. LB 168 thus interferes with the careful balance that Congress established in the 340B program The Supremacy Clause prohibits precisely this type of interference.

LB 168 Violates the Contracts Clause

76. LB 168 also violates the Contracts Clause of the U.S. Constitution. Article I, section 10, clause 1 of the Constitution provides that "No State shall . . . pass any . . . Law impairing the Obligation of Contracts." Courts have interpreted the Contracts Clause to require a three-part test to balance the State's obligation not to impair contracts with the State's interest in public welfare. *See Equip. Mfrs. Inst. v. Janklow*, 300 F.3d 842, 850 (8th Cir. 2002). First, the court asks "whether the state law has, in fact, operated as a substantial impairment on pre-existing contractual relationships." *Janklow*, 300 F.3d at 850. Second, if the court finds substantial impairment, it must examine whether the State has a "significant and legitimate public purpose behind the regulation." *Id.* (quoting *Educ. Emps. Credit Union v. Mutual Guar. Corp.*, 50 F.3d 1432, 1438 (8th Cir. 1995)). Third, if the State presents a legitimate justification for the impairment, the court "must determine 'whether the adjustment of the rights and responsibilities of contracting parties [is based] upon reasonable conditions and [is] of a character appropriate to the public purpose justifying [the legislation's] adoption." *Id.* (quoting *Energy Rsrvs. Grp., Inc. v. Kan. Power & Light Co.*, 459 U.S. 400, 412 (1983) (alterations in original)).

77. LB 168 fails at every stage of this test. LB 168 substantially impairs a contractual relationship. As explained above, the 340B program operates through contracts, which are called pharmaceutical pricing agreements (PPAs). PPAs are "uniform agreements that recite the responsibilities § 340B imposes . . . on drug manufacturers and the Secretary of HHS." *Astra USA*, 563 U.S. at 113. While PPAs are not "transactional, bargained-for contracts," *id.*, they nonetheless announce the parties' rights and obligations like any other contract, and manufacturers like AstraZeneca are entitled to rely on the PPA's terms when developing their business. Among those terms is the requirement that manufacturers offer discounted drugs only for sales to a specifically delineated set of "covered entities." As the Third Circuit held, and the D.C. Circuit later underscored, neither the 340B statute nor the PPA requires AstraZeneca to make 340B discounts available for sales at "an unlimited number of contract pharmacies." *Novartis Pharms.*, 102 F.4th at 461 (quoting *Sanofi Aventis*, 58 F.4th at 706).

78. LB 168 operates as a substantial impairment of AstraZeneca's PPA with the HHS Secretary. AstraZeneca joined the 340B program with the expectation and understanding that it would be required to offer discounts only for a limited category of sales, and it accepted that obligation. LB 168 seeks to unilaterally expand AstraZeneca's obligations under that contract—without AstraZeneca's consent—by requiring AstraZeneca to offer discounts for an entirely new category of sales: contract pharmacy sales.

79. The U.S. Supreme Court has held that similar expansions of beneficiaries to a contract constitute substantial impairment under the Contracts Clause. *See Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 245-46 (1978) (Contracts Clause prohibited State from requiring company to provide additional pension benefits after it had agreed to provide pension benefits under specific contractual conditions); *see also United Healthcare Ins. Co. v. Davis*, 602 F.3d 618,

630 (5th Cir. 2010) (Contracts Clause prohibited state from enacting legislation increasing obligations on companies that had agreed to insure state employees under specific conditions).

80. LB 168 impairs AstraZeneca's contracts in other ways, too. AstraZeneca agreed by contract to participate in a regulatory regime that allowed it to conduct audits to facilitate ADR claims. But LB 168's data-collection restriction severely limits AstraZeneca's ability to gather information necessary for pre-ADR audits, frustrating another critical component of its contractual agreement under the PPA and further increasing the burdens of participating in the 340B program.

81. Any justification Nebraska might offer for LB 168 would be insufficient under the Contracts Clause. Nebraska cannot claim that its law is necessary to provide access to 340B drugs to covered entities and their patients, because AstraZeneca's policy already ensures that every covered entity is offered those drugs at a discounted price. Indeed, AstraZeneca's policy goes further, allowing covered entities to designate a single contract pharmacy if it does not have an on-site pharmacy.

82. Nebraska has no legitimate justification for requiring discounts for unlimited contract pharmacy sales, which will advance the economic interests of for-profit entities at the expense of companies like AstraZeneca, particularly where Congress itself has not required them. *See Ass'n of Equip. Mfrs. v. Burgum*, 932 F.3d 727, 732 (8th Cir. 2019) (noting that "the Contract Clause prohibits special-interest redistributive laws, even if the legislation might have a conceivable or incidental public purpose").

83. Nor can Nebraska justify LB 168 as a cost-reduction mechanism for patients. Studies show that most 340B discounts to contract pharmacies are *not* passed on to patients, who must pay full price for their drugs. *See* ¶ 33, *supra*.

84. Finally, even if Nebraska could articulate a legitimate justification for LB 168's impairment of AstraZeneca's PPA, that justification would not be reasonable and necessary to achieve the State's goals.

LB 168 Violates the Takings Clause

85. The Takings Clause of the U.S. Constitution provides that "private property" may not "be taken for public use, without just compensation." U.S. Const. amend. V.

86. Under the Takings Clause, although the government may take private property "for public use" so long as it pays "just compensation," the government may never take private property for *private* use, regardless of the amount of compensation paid. As the U.S. Supreme Court has explained, "the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*," a prohibition that applies regardless of whether "*A* is paid just compensation." *Kelo*, 545 U.S. at 477. Such takings for private use are always unlawful, since "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

87. LB 168 takes the private property of manufacturers like AstraZeneca for private, not public, use. The law forces manufacturers to transfer their prescription drugs to other private (non-governmental) entities—namely, to covered entities and the pharmacies with which they contract—at prices that AstraZeneca would not otherwise offer (and is not required to offer under federal law).

88. This forced transfer would be unlawful even if manufacturers were paid just compensation for these contract pharmacy sales. *See id.* But manufacturers are *not* justly compensated for the forced transfers covered by the law: The law requires manufacturers to make these transfers at steeply discounted prices, well below fair market value.

89. This forced transfer results in the "physical appropriation" of manufacturers' prescription drugs by contract pharmacies and covered entities, and it therefore constitutes "a *per se* taking." *Cedar Point Nursery v. Hasid*, 594 U.S. 139, 149 (2021).

90. But even if LB 168 did not involve a physical appropriation, it would still constitute a regulatory taking because it (1) has a profound economic impact on the value of the property subject to the law; (2) significantly interferes with manufacturers' investment-backed expectations; and (3) forces manufacturers to transfer title to their property, depriving them of the full use and enjoyment of that property. *See Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 124 (1978).

91. LB 168 accordingly violates the Takings Clause of the U.S. Constitution.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – LB 168 is Preempted by Federal Patent Law Supremacy Clause, U.S. Const. art. VI, cl. 2)

92. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

93. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law." *Felder*, 487 U.S. at 138. Moreover, the Constitution assigns exclusive authority to regulate patents to the U.S. Congress. With respect to pharmaceuticals, Congress has enacted comprehensive legislation establishing the scope of patent rights under federal law. Thus, state laws that cap or fix drug prices are preempted by federal patent law because they "re-balance the statutory framework of rewards and incentives . . . in effect diminishing the reward to patentees in order to provide greater benefit to . . . drug consumers." *BIO*, 496 F.3d at 1374.

94. LB 168 requires manufacturers to make 340B discounts available for unlimited contract pharmacy sales, and it empowers Defendants to pursue purported violations of the statute. As applied to AstraZeneca's patented products, those provisions are preempted by federal patent law under the Supremacy Clause.

95. The obligation imposed by LB 168 on manufacturers—to offer 340B discounts for unlimited contract pharmacy sales—caps the prices at which manufacturers can sell their patented drugs and constrains manufacturers' "opportunity" to take advantage of the benefits of exclusivity "during the patent's term." *Id.* at 1372. The Act therefore impermissibly seeks to "re-balance" the "rewards and incentives" embodied in the federal patent laws in a manner that is beyond a state's powers. *Id.* at 1374. LB 168 is therefore preempted by federal patent law under the Supremacy Clause as applied to AstraZeneca's patented products.

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – LB 168's Data-Collection Restriction is Preempted by Section 340B under the Supremacy Clause, U.S. Const. art. VI, cl. 2)

96. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

97. The Supremacy Clause, U.S. Const. art. VI, cl. 2, prohibits a State from enacting any law "which interferes with or is contrary to federal law," quoting *Felder*, 487 U.S. at 138 (citation omitted). LB 168's data-collection restriction is preempted by the 340B statute under the Supremacy Clause.

98. LB 168's data-collection restriction creates an obstacle to the accomplishment and execution of Congress's objectives for the 340B statute. Section 340B includes a comprehensive regime for enforcement and management of the program, which includes the ADR process, audits, and civil monetary penalties. LB 168's data-collection restriction inhibits manufacturers' access

to Congress's enforcement regime, and also prevents manufacturers from enforcing their federal right to avoid paying duplicate discounts under the 340B program and the IRA.

99. LB 168 thus interferes with the operation of federal law. It also imposes significant new costs for participating in a federal benefits program, thereby "exert[ing] an extraneous pull on the scheme established by Congress" and "skew[ing]" the "delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348, 353. LB 168's attempt to insert into Congress's program a layer of enforcement by state officials under Nebraska law frustrates Congress's purposes and interferes with the carefully specified federal regime it created.

100. For these reasons, LB 168's data-collection restriction is preempted by federal law under the Supremacy Clause.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – LB 168 Violates the Contracts Clause, U.S. Const., art. I, § 10, cl. 1)

101. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

102. Under the Contracts Clause, U.S. Const. art. I, § 10, cl. 1, "[n]o State shall . . . pass any . . . Law impairing the Obligation of Contracts." The Contracts Clause thus prohibits States from enacting legislation that "operate[s] as a substantial impairment on pre-existing contractual relationships." *Equip. Mfrs. Inst.*, 300 F.3d at 850.

103. LB 168 violates the Contracts Clause. It substantially impairs AstraZeneca's PPA with the HHS Secretary by requiring AstraZeneca to offer 340B discounts for unlimited contract pharmacy sales, thus purporting to substantially expand AstraZeneca's obligations under the agreement beyond what the agreement itself provides.

104. Nebraska has no valid justification for impairing AstraZeneca's PPA. AstraZeneca's policy ensures that every covered entity is offered 340B drugs at statutorily required prices. The policy also allows covered entities without an on-site pharmacy to utilize a single contract pharmacy, which is more than the statute requires. Compelling AstraZeneca to provide 340B-discounted drugs for unlimited contract pharmacy sales advances the economic interests of for-profit pharmacies at AstraZeneca's expense, with little to no benefit to 340B patients.

105. Even if Nebraska could identify a legitimate justification for impairing AstraZeneca's PPA, it would not be reasonable and necessary to achieve the State's goals.

106. LB 168 is also unconstitutional under the Contracts Clause to the extent it requires AstraZeneca to offer 340B discounts for sales at contract pharmacies that do not qualify as covered entities, and which therefore are not included within the anticipated or actual scope of the PPA that AstraZeneca signed with the HHS Secretary.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – LB 168 Violates the Takings Clause, U.S. Const., amend. V)

107. Plaintiff realleges and incorporates by reference all prior and subsequent paragraphs.

108. Under the Takings Clause of the Fifth Amendment of the U.S. Constitution, the government may not take "private property" for private use—such as requiring the transfer of ownership from one private party to another—even if just compensation is paid.

109. LB 168 takes private property for private use by forcing manufacturers to transfer 340B-discounted drugs—including relinquishing title and control of the drugs—to private, non-governmental entities (covered entities and their contract pharmacies) at non-commercial prices that AstraZeneca would not otherwise offer.

110. LB 168 also denies manufacturers just compensation because it requires that their drugs be transferred to these private entities at below-market prices.

111. The forced transfer of drugs under LB 168 constitutes a taking per se or, in the alternative, a regulatory taking.

112. LB 168 is therefore unconstitutional under the Takings Clause.

PRAYER FOR RELIEF

NOW, THEREFORE, AstraZeneca requests a judgment in its favor against the Nebraska Attorney General as follows:

A. Declare that LB 168 is preempted by federal patent law and is therefore null, void, and unenforceable;

B. Declare that LB 168's data-collection restriction is preempted by Section 340B and is therefore null, void, and unenforceable;

C. Declare that LB 168 is unconstitutional as applied to AstraZeneca under the Contracts Clause of the U.S. Constitution;

D. Declare that LB 168 is unconstitutional as applied to AstraZeneca under the Takings Clause of the U.S. Constitution;

E. Declare that AstraZeneca is not required to offer 340B discounts for unlimited contract pharmacy sales under Nebraska law;

F. Issue preliminary and permanent injunctive relief preventing Defendants from implementing or enforcing LB 168 against AstraZeneca or any of its affiliates, officers, agents, or contractors;

G. Issue preliminary and permanent injunctive relief preventing Defendants from seeking civil penalties, equitable relief, or any other remedy based on any alleged

violation of LB 168 by AstraZeneca or any of its affiliates, officers, agents, or contractors;

H. Award AstraZeneca reasonable attorneys' fees and costs, as appropriate; and

I. Grant such other and further relief as the Court may deem appropriate.

DATED this 10th day of June, 2025.

Respectfully submitted,

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